UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Elizabeth Kahn, 16-17039	)	

ORDER AND REASONS

Before the Court is Defendants' Motion to Exclude Supplemental Opinion of Dr. Laura Plunkett (Doc. 12575). The Court held oral argument on the Motion on July 9, 2021. For the following reasons, the Motion is **GRANTED IN PART** and **DENIED IN PART.**

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second trial is set for August 23, 2021.[2]

Plaintiff Elizabeth Kahn, the second bellwether plaintiff, plans to call Dr. Laura Plunkett as a witness at trial. Dr. Plunkett is pharmacologist and

[1] Docetaxel is the generic version of Taxotere.
[2] The second trial was continued due to the COVID-19 pandemic.

toxicologist. On January 13, 2021, this Court issued an Order and Reasons ruling on Sanofi's Motion to Exclude Expert Testimony of Dr. Laura Plunkett.[3] Since that ruling, Plaintiff has learned that her original labeling expert, Dr. David Kessler, is no longer available to provide testimony in this case. Because of this, Plaintiff has now designated Dr. David Ross as well as Dr. Plunkett to opine on the adequacy of the Taxotere label. In the instant Motion, Sanofi seeks to exclude Dr. Plunkett's supplemental testimony relating to labeling. Plaintiff Kahn opposes the Motion.

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.[4]

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*[5] and *Kumho Tire Co. v. Carmichael*.[6] The threshold inquiry in determining whether an individual may offer expert

[3] Doc. 11823.
[4] FED. R. EVID. 702.
[5] 509 U.S. 579 (1993).
[6] 526 U.S. 137 (1999).

testimony under Rule 702 is whether the individual has the requisite qualifications.[7] After defining the permissible scope of the expert's testimony, a court next assesses whether the opinions are reliable and relevant.[8] As the "gatekeeper" of expert testimony, the trial court enjoys broad discretion in determining admissibility.[9]

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert's testimony is valid.[10] The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.[11] Courts should exclude testimony based merely on subjective belief or unsupported speculation.[12] Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.[13] "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."[14] After assessing reliability, a court evaluates relevance.[15] In doing so, a court must determine whether the expert's reasoning or methodology "fits" the facts of the case and will thereby assist the trier of fact in understanding the evidence.[16]

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[7] Wagoner v. Exxon Mobil Corp., 813 F. Supp. 2d 771, 799 (E.D. La. 2011). *See also* Wilson v. Woods, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").
[8] *See* United States v. Valencia, 600 F.3d 389, 424 (5th Cir. 2010). *See also* Wellogix, Inc. v. Accenture, L.L.P., 716 F.3d 867, 881–82 (5th Cir. 2013).
[9] *Wellogix*, 716 F.3d at 881.
[10] *See Daubert*, 509 U.S. at 592–93.
[11] *See* Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998).
[12] *See Daubert*, 509 U.S. at 590.
[13] *See id.* at 596.
[14] *Id.*
[15] Burst v. Shell Oil Co., 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).
[16] *Id.*

LAW AND ANALYSIS

On January 13, 2021, this Court issued an Order and Reasons ruling on Sanofi's Motion to Exclude Expert Testimony of Dr. Laura Plunkett.[17] The Court wrote that "Dr. Plunkett did not conduct an analysis to assess general causation, so she may not suggest to the jury that Taxotere can cause permanent alopecia."[18] In pertinent part, the Court ruled that Dr. Plunkett may not testify (1) that Taxotere carries an independent risk of permanent alopecia; or (2) that when used in combination with other drugs, Taxotere is a "substantial contributing factor" to permanent alopecia. Sanofi argues that Dr. Plunkett's supplemental report on labeling should be excluded on these same grounds.

In her supplemental report, Dr. Plunkett opines that Sanofi should have updated its Taxotere label to warn of permanent alopecia before Kahn received her treatment in 2008.[19] Dr. Plunkett writes that "the standard in terms of when to include information in a drug's label is not a causation standard but, instead, the fact that some information exists such there is a reason to believe that the drug and the reaction are related to one another."[20] She further claims that she is "not offering causation opinions in this case."[21] In explaining her conclusion that a label change was warranted, however, she states that:

> [T]he weight-of-the-evidence indicates that it is biologically plausible that Taxotere/ docetaxel can cause CIPAL/ PCIA [permanent chemotherapy-induced alopecia] when the drug is used as an adjuvant to treat early stage breast cancer, that the risk of permanent, irreversible alopecia is not rare, that Taxotere/ docetaxel use carries an independent risk of CIPAL/ PCIA[.][22]

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[17] Doc. 11823.
[18] *Id.* at 5.
[19] Doc. 12739 at 6; Doc. 12575-4 at 18.
[20] Doc. 12575-4 at 14.
[21] *Id.* at 13.
[22] *Id.* at 18.

Elsewhere in her supplemental report, Dr. Plunkett concludes from a certain study that Taxotere "carried an independent risk of CIPAL/PCIA in this case series and was a substantial contributing factor to the condition in the women studied."[23]

Sanofi correctly argues that these opinions are just the sort of causation opinions that this Court previously ruled inadmissible. The Court explained:

> [S]tating that Taxotere carries an independent risk of permanent alopecia is indistinguishable from stating that Taxotere alone can cause alopecia. Dr. Plunkett, therefore, must take care to state only that Taxotere has been *associated* with an independent risk of permanent hair loss.
>
> For similar reasons, the Court will not permit Dr. Plunkett to opine that when used in combination with other drugs, Taxotere is a "substantial contributing factor" to permanent alopecia. This opinion would "invade the province of the jury." The jury will be tasked with determining proximate causation, and in the *Earnest* trial, the jury was instructed, per Louisiana law, to consider whether "Defendants' conduct was a 'substantial contributing factor' in bringing about the [alleged injury]." If Dr. Plunkett were to tell the jury that Taxotere was a "substantial contributing factor" that led to permanent alopecia in patients who took combination regimens, the jury may see this as a direct answer to the question of proximate causation. For these reasons, Dr. Plunkett may not testify that in combination regimens, Taxotere is a "substantial contributing factor" to permanent alopecia.[24]

Although Dr. Plunkett makes clear that updating a drug label does not require proof of causation, she nonetheless veers into causation in explaining why Sanofi should have updated its label. Just as in her original report, Dr. Plunkett has not performed a causation analysis. Rather, she has performed an association analysis. The Court, as it previously ruled, will not allow Dr.

[23] *Id.* at 19.
[24] Doc. 11823 at 5–6.

Plunkett to opine that Taxotere causes, carries an independent risk, or is a substantial contributing factor to permanent alopecia.

That said, the Court finds portions of Dr. Plunkett's opinion appropriate. Specifically, she opines that:

> Taxotere/ docetaxel use is associated with an increased risk of CIPAL/ PCIA as compared to other drugs used in breast cancer treatment. Thus, the evidence discussed in my March Report provides important support for my new opinion that there is a basis in the Taxotere database, importantly including clinical trial evidence, "to believe there is a causal relationship between the drug and the occurrence of the adverse event."[25]

The Court finds that Dr. Plunkett has performed the appropriate analysis to offer this opinion. This opinion does not speak to causation but rather to association and whether there was a basis to believe a causal relationship existed. Accordingly, these opinions are appropriate in light of the analysis she performed and do not run afoul of this Court's prior order.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude Supplemental Opinion of Dr. Laura Plunkett (Doc. 12575) is **GRANTED IN PART** and **DENIED IN PART**.

New Orleans, Louisiana, this 23rd day of July, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

[25] Doc. 12575-4 at 18.